

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION

MERZ NORTH AMERICA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 5:15-CV-262-H-KS
	)	
CYTOPHIL, INC., d/b/a REGENSCIENTIFIC,	)	
	)	
Defendant.	)	
<hr/>	)	
CYTOPHIL, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 5:16-CV-745-H-KS
	)	
MERZ NORTH AMERICA, INC.,	)	
	)	
Defendant.	)	

**MEMORANDUM & RECOMMENDATION**

This matter is before the court on Merz North America, Inc.’s motion to dismiss *Cytophil, Inc. v. Merz North America, Inc.*, No. 5:16-CV-745-H-KS, pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure [DE #35], the motion having been referred to the undersigned by Senior United States District Judge Malcolm J. Howard for memorandum and recommendation pursuant to 28 U.S.C. § 636(b)(1)(B). An appropriate response and reply have been filed, and the motion is ripe for adjudication.

**BACKGROUND**

These consolidated actions involve U.S. Patent No. 6,537,574 (“the ‘574 Patent”) concerning a soft tissue augmentation material, which patent is held by Merz North America, Inc.

(“Merz”). Cytophil, Inc. (“Cytophil”) is a competitor of Merz and an alleged infringer of the ‘574 Patent.

On April 6, 2016, Cytophil filed an action against Merz in the United States District Court for the Eastern District of Wisconsin. *Cytophil, Inc. v Merz North America, Inc.*, No. 2:16-CV-423-LA (E.D. Wis. filed Apr. 6, 2016). In its complaint, Cytophil asserts claims of false patent marking, Sherman Act violations, and commercial disparagement. The action was transferred to this district on August 16, 2016, and restyled as *Cytophil, Inc. v Merz North America, Inc.*, No. 5:16-CV-745-H-KS (E.D.N.C.) (“*Cytophil* Action”). On August 30, 2016, the court consolidated the action with another action between the parties, which was pending before the court. *See Merz North America, Inc. v. Cytophil*, No. 5:15-CV-262-H-KS (E.D.N.C. filed June 18, 2015) (“*Merz* Action”).

Prior to transfer, Merz filed the motion presently before the court in which Merz seeks to dismiss the *Cytophil* Action pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.

## **DISCUSSION**

### **I. False Patent Marking Claims (Counts I & II)**

Merz moves to dismiss Cytophil’s false marking claims on the ground Cytophil lacks both constitutional and statutory standing to bring the claims. Article III of the United States Constitution grants federal courts power to hear only “Cases” and “Controversies.” U.S. CONST. art. III, § 2. “Standing to sue is a doctrine rooted in the traditional understanding of a case or controversy.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). It limits the category of litigants who may seek redress in federal court in order to prevent the judiciary from usurping the powers of the legislative executive branches. *Id.*

Standing is a jurisdictional requirement, and the plaintiff bears the burden of establishing standing. At the pleading stage, a plaintiff must clearly allege facts demonstrating the following: (1) that it has suffered “injury-in-fact”; (2) that the injury is “fairly traceable to the challenged conduct of the defendant”; and (3) that the injury will likely “be redressed by a favorable judicial decision.” *Spokeo*, 136 S. Ct. at 1547.

Cytophil’s false marking claim is also subject to a statutory standing requirement imposed by 35 U.S.C. § 292. With the passage of the America Invents Act in 2011, Congress amended § 292 to eliminate *qui tam* actions and require that private plaintiffs suing under the statute have actually suffered competitive injury as a result of the defendant’s false marking. Although not defined by statute, “competitive injury” is generally considered “[a] wrongful economic loss caused by a commercial rival, such as the loss of sales due to unfair competition” or “a disadvantage in a plaintiff’s ability to compete with a defendant, caused by the defendant’s unfair competition.” *Sukumar v. Nautilus, Inc.*, 785 F.3d 1396, 1400 (Fed. Cir. 2015) (quoting BLACK’S LAW DICTIONARY (9th ed. 2009)). It is not confined to losses incurred by those already in the market. *Sukumar*, 785 F.3d at 1400. “[A] potential competitor may suffer ‘a disadvantage in [its] ability to compete’ if another’s actions impair its ability to enter the market.” *Id.* However, as the Federal Circuit noted in *Sukumar*, not all potential competitors are included:

A potential competitor can only suffer a *competitive* injury if it engages in competition. Dreaming of an idea but never attempting to put it into practice is insufficient. Otherwise, market entry is too speculative and, thus, competition cannot be harmed by the false marking. Likewise, sometimes a falsely marked product is also properly marked with other patents. In that case, a potential competitor must show that the falsely marked patents deterred market entry, but that—for some reason—the properly marked patents did not deter market entry. Therefore, an injury is only a “competitive injury” if it results from competition, and a potential competitor is engaged in competition if it has attempted to enter the market, which includes intent to enter the market and action to enter the market. And, for the sake of completeness, an entity has standing under § 292(b) if it can demonstrate competitive injury that was caused by the alleged false marking.

*Sukumar*, 785 F.3d at 1402.

A showing of competitive injury under § 292 would necessarily amount to an injury-in-fact for purposes of constitutional standing. *See Reynard v. Griffin*, No. 2:14-CV-2261, 2015 WL 12743605, at \*2 (S.D. Ohio Aug. 18, 2015). Accordingly, the undersigned begins by addressing whether Cytophil has sufficiently alleged that it meets the statutory standing requirements of § 292.

In its complaint, Cytophil alleges it is a direct competitor of Merz in two, separate, specialized medical-device markets: (1) “gel-only injectable vocal cord medialization systems that are volumizing soft tissue filler products classified under the United States Food and Drug Administration’s ‘MIX’ product code” (“Gel Product Market”) (Compl. [DE #1] ¶ 12);<sup>1</sup> and (2) “other injectable vocal cord medialization systems that are volumizing soft tissue filler products classified under the United States Food and Drug Administration’s ‘MIX’ product code, specifically the market for such injectable systems that consist of Calcium Hydroxylapatite . . . particles suspended in an aqueous gel carrier” (“Particle Suspension Product Market”) (Compl. ¶ 15).

Cytophil identifies the parties’ various competitive products and the markets to which they belong. With respect to the Gel Product Market, Cytophil alleges as follows: “Cytophil manufacturers, offers and sells a product known as RENÚ® GEL, and Merz manufactures, offers and sells competing products known variously as Prolaryn Gel, Prolaryn Voice Gel and Radiesse Voice Gel.” (Compl. ¶ 13.) Cytophil includes similar allegations regarding the Particle Suspension Product Market: “Cytophil manufacturers, offers and sells a product known as RENÚ® VOICE,

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<sup>1</sup> Citations to the complaint and other court documents are to those filed in the Cytophil Action, No. 5:16-CV-745-H-KS.

and Merz manufactures, offers and sells competing products known variously as Prolaryn Plus, Radiesse Voice and, simply, Radiesse.” (Compl. ¶ 16.) According to the complaint, the competing Particle Suspension Products are the same, “the only difference between such products being the product names.” (Compl. ¶ 52.)

Cytophil asserts that neither Merz’s Gel Products nor its Particle Suspension Products are covered by the ‘574 Patent or used in the method of the ‘574 Patent and that Merz is fully aware and has always been fully aware of that fact. (Compl. ¶¶ 38, 40, 56, 59.) Cytophil claims that Merz, with full knowledge of these facts, has stated falsely that its Gel Products and Particle Suspension Products are covered by the ‘574 Patent (Compl. ¶¶ 62, 69) and has falsely marked the packaging of the products as protected by the ‘574 Patent (Compl. ¶¶ 63, 70).

Cytophil further alleges that Merz has engaged in false marking for the purpose of “deceiv[ing] the public” by “creating a false public impression that Merz has an exclusive right to make, offer and sell” its Gel Products and Particle Suspension Products (Compl. ¶¶ 65, 72) and “to create a false public impression as to the scope of the ‘574 Patent; and to suppress and chill competition in [the Gel Product Market and the Particle Suspension Product Market] in the United States” (Compl. ¶¶ 65, 72). Elsewhere in its complaint, Cytophil alleges that Merz has over 98% of the share in both markets (Compl. ¶¶ 14, 17, 91, 100) and has “acquired and maintained monopoly power in [both product markets]” as a result of its unlawful actions (Compl. ¶¶ 91, 100). Finally, Cytophil asserts it has been unfairly and unlawfully disadvantaged by Merz’s actions (Compl. ¶¶ 66, 73), having been prevented from obtaining more than its current market share of less than 2%.

Cytophil’s false patent marking claims are tied closely to its other claims, including its Sherman Act claims. Read as a whole, it is clear from the complaint that Cytophil is claiming that

Merz has monopolized the Gel Product Market and the Particle Suspension Product Market, in part, by falsely marking its patents, advertising the products as patented, and falsely accusing Cytophil of infringing its patent. Cytophil claims that Merz's actions have damaged Cytophil's reputation and the reputation of its products and caused Cytophil pecuniary loss. These allegations sufficiently allege competitive injury to withstand Merz's motion to dismiss.

## **II. Sherman Act Claims (Counts III & IV)**

Merz moves to dismiss Cytophil's Sherman Act antitrust claims for failure to state a claim. Merz contends that Cytophil has not pled sufficient facts to plausibly allege either a relevant market or an antitrust injury under the Sherman Act.

Section 2 of the Sherman Act provides that "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person . . . to monopolize any part of the trade" is guilty of an offense and subject to penalties. 15 U.S.C. § 2. A § 2 monopolization offense has two elements: "(1) the possession of monopoly power; and (2) willful acquisition or maintenance of that power – as opposed to simply superior products or historic accidents." *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 441 (4th Cir. 2011). Attempted monopolization is "(1) the use of anticompetitive conduct; (2) with specific intent to monopolize; and (3) a dangerous probability of success." *Id.*

### **A. Relevant Market**

"To run afoul of Section 2, a defendant must be guilty of illegal conduct 'to foreclose competition, to gain a competitive advantage, or to destroy a competitor.'" *E.I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d at 441 (quoting *Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. at 451, 482–83 (1992)). Thus, a claim of monopolization or attempted monopolization requires, as a threshold, a relevant market. *Consul, Ltd. v. Transco Energy Co.*,

805 F.2d 490, 493 (4th Cir. 1986). A relevant market is comprised of two components – a geographic market and a product market. *Id.* “[T]he relevant geographic market is the area in which buyers or sellers of the relevant product effectively compete.” *Consul, Ltd.*, 805 F.2d at 495 (citing *Satellite Television v. Continental Cablevision*, 714 F.2d 351, 357 (4th Cir.1983)). “The relevant product market consists of all products that are ‘reasonably interchangeable by consumers for the same purposes.’” *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956). The relevant market may encompass an entire nation or a single metropolitan area depending upon the commercial realities of the market and competition. *E.I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d at 442-43.

Market definition is a fact-sensitive determination. “[D]ismissals at the pre-discovery, pleading stage [are] relatively rare and . . . generally limited to’ certain types of ‘glaring deficiencies,’” such as where “‘the complaint either: (1) fails to allege a geographic market or the boundaries of a relevant geographic market; (2) defines a geographic market in an unreasonably and implausibly narrow manner; or (3) alleges a contradictory and vague delineation of the relevant geographic market.’” *E.I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d at 444 (quoting *Allen v. Dairy Farmers of Am., Inc.*, 748 F. Supp. 2d 323, 339 (D. Vt. 2010)).

As set forth above, Cytophil’s complaint identifies two, separate, specialized medical-device product markets: (1) the Gel Product Market and (2) the Particle Suspension Product Market. Cytophil argues that the product markets are defined not only by the averments of its complaint, but also by the United States Food and Drug Administration’s “MIX” product classification code for vocal cord medialization systems. As to Count III, the product market is defined as the market “for gel-only injectable vocal cord medialization systems that are volumizing soft tissue filler products classified under the United States Food and Drug Administration’s

“MIX” product code.” (Compl. ¶ 12.) For purposes of Count IV, the product market pled is the market for “MIX”-type products that are injectable vocal cord medialization systems that are volumizing soft tissue filler products consisting of Calcium Hydroxylapatite particles suspended in an aqueous gel carrier. (Compl. ¶ 15.) In both instances, the geographic market is alleged to be the United States. The undersigned sees no “glaring deficiencies” with Cytophil’s market allegations and therefore determines that dismissal at this stage of the proceedings, prior to any factual inquiry into the commercial realities of the market, would be improper.

#### B. Antitrust Injury

In addition to monopolizing conduct, a plaintiff asserting a Sherman Act § 2 claim must plausibly allege an antitrust injury caused by the defendant’s anticompetitive conduct. *See Dickson v. Microsoft Corp.*, 309 F.3d 193, 211 (4th Cir. 2002). An antitrust injury is one where the injury is “of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful.” *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990). “[I]njury, although causally related to an antitrust violation, nevertheless will not qualify as ‘antitrust injury’ unless it is attributable to an anti-competitive aspect of the practice under scrutiny.” *Id.* (citing *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 109-110 (1986)).

Here, Cytophil alleges an injury to competition that the antitrust laws were intended to prevent. This is not a case where the plaintiff complains merely of lost profits due to vigorous competition. *See Cargill, Inc.*, 479 U.S. at 117 (“[T]he threat of loss of profits due to possible price competition following a merger does not constitute a threat of antitrust injury.”). Nor is it a case where the plaintiff states in a wholly conclusory fashion that it has been damaged “by means of anticompetitive and/or predatory conduct” of the defendant. *See Tamburo v. Dworkin*, 601 F.3d 693, 699 (7th Cir. 2010) (complaint alleging, without further factual support, that “defendants

possessed ‘monopoly power in the relevant market of dog breeding data,’ which they acquired ‘by means of anticompetitive and/or predatory conduct,’” and that plaintiff “has been damaged” thereby held insufficient to state a federal antitrust claim).

Cytophil alleges that Merz falsely marked and advertised its products as patented (Compl. ¶ 76, 98), brought sham litigation against Cytophil (Compl. ¶ 77-79), and falsely accused Cytophil of infringing the ‘574 Patent in statements made to the public, including to the press and market participants (Compl. ¶ 80-89), for the purpose of restraining competition (Compl. ¶ 90, 98-99). Cytophil asserts that these actions have damaged Cytophil’s reputation and the reputation of its products and impaired Cytophil’s ability to enter the markets or increase its market share, causing Cytophil pecuniary loss. (Compl. ¶ 80-87, 92-93, 95, 101, 102, 104.) In sum, Cytophil asserts that Merz has monopolized the market to Cytophil’s detriment by wrongfully using and enforcing its ‘574 Patent. Cytophil’s complaint contains sufficient facts to plausibly state an antitrust injury at the pleading stage. Accordingly, it is recommended that Merz’s motion to dismiss Cytophil’s § 2 claims be denied.

### **III. Commercial Disparagement Claim (Count V)**

Finally, Merz moves to dismiss Count V of Cytophil’s complaint for failure to state a claim upon which relief can be granted. Merz contends that North Carolina law does not recognize a cause of action for “commercial disparagement” and that Cytophil’s claim, even if construed as a defamation claim, is subject to dismissal because it fails to state with specificity factual details concerning the alleged false statements. (Merz’s Mem. Supp. Mot. Dismiss [DE #36] at 19-20; Merz’s Reply Mot. Dismiss [DE #84] at 13-14.)

In response, Cytophil states that Count V was pled using the “commercial disparagement” nomenclature recognized by Wisconsin courts because the claim was originally filed in the United

States District Court for the Eastern District of Wisconsin. Cytophil argues, however, that its claim, regardless of the nomenclature used, is viable under North Carolina law – “[t]he concept of ‘commercial disparagement’ obviously embraces and includes trade disparagement and product disparagement, which North Carolina courts recognize as viable claims.” (Cytophil’s Resp. Mot. Dismiss [DE #81] at 12.)

In light of the venue change and because it is unclear what the basis is, if any, for Cytophil’s disparagement claim under North Carolina law (*i.e.* statutory or common law), the undersigned recommends that Count V be dismissed without prejudice and that Cytophil be given an opportunity to amend its pleading to assert its claim, if any, under North Carolina law.

### **CONCLUSION**

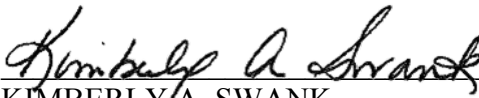
For the foregoing reasons, it is RECOMMENDED that Merz’s motion to dismiss [DE #35] be GRANTED IN PART and DENIED IN PART. As set forth more fully above, it is RECOMMENDED that Count V of Cytophil’s complaint be DISMISSED WITHOUT PREJUDICE and that Cytophil be given fourteen days from the court’s ruling within which to amend its pleading to reassert its claim, if any, under North Carolina law.

IT IS DIRECTED that a copy of this Memorandum and Recommendation be served on each of the parties or, if represented, their counsel. Each party shall have until **March 7, 2017**, to file written objections to the Memorandum and Recommendation. The presiding district judge must conduct his or her own review (that is, make a *de novo* determination) of those portions of the Memorandum and Recommendation to which objection is properly made and may accept, reject, or modify the determinations in the Memorandum and Recommendation; receive further evidence; or return the matter to the magistrate judge with instructions. *See, e.g.*, 28 U.S.C.

§ 636(b)(1); Fed. R. Civ. P. 72(b)(3); Local Civ. R. 1.1 (permitting modification of deadlines specified in local rules), 72.4(b), E.D.N.C.

A party that does not file written objections to the Memorandum and Recommendation by the foregoing deadline, will be giving up the right to review of the Memorandum and Recommendation by the presiding district judge as described above, and the presiding district judge may enter an order or judgment based on the Memorandum and Recommendation without such review. In addition, a party's failure to file written objections by the foregoing deadline may bar the party from appealing to the Court of Appeals from an order or judgment of the presiding district judge based on the Memorandum and Recommendation. *See Wright v. Collins*, 766 F.2d 841, 846-47 (4th Cir. 1985).

This 21st day of February 2017.

  
KIMBERLY A. SWANK  
United States Magistrate Judge